



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donald L. Wise, Debra J. Trantolo, David D. Hile, and Stephen A. Doherty

Serial No.: 10/613,975

Art Unit: 1642

Filed: July 3, 2003

Examiner: Not Yet Assigned

For: *VACCINES TO INDUCE MUCOSAL IMMUNITY*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eight (8) pages of Form PTO-1449 and copies of the sixty-eight documents cited therein.

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U.S. Patents

	<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
/KS/	5,429,822	07-04-1995	Gresser, et al.	424/426
/KS/	5,456,917	10-10-1995	Wise, et al.	424/426

/Khatol Shahnan Shah/

01/14/2008

Publications

ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," *Pharm. Res.* 10(7): 945-953 (1993).

ANCHORDOQUY & KOE, "Physical stability of nonviral plasmid-based therapeutics," *J. Pharm. Science.* 89(3): 289-296 (2000).

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DOOLAN, et al., "Circumventing genetic restriction of protection against malaria with multigene DNA immunization: CD8⁺ T cell-, Interferon γ -, and nitric oxide-dependent immunity," *J. Exp. Med.* 183: 1739-1746 (1996).

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ERMAK, et al., "Uptake and transport of copolymer biodegradable microspheres by rabbit Peyer's patch M cells," *Cell Tiss. Res.* 279: 433-436 (1995).

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GORDON, et al., "Proteolytic activation of bacterial toxins by eukaryotic cells is performed by furin and by additional cellular proteases," *Infect. Immun* 63: 82-87 (1995).

GU, et al., "Protection against anthrax toxin by vaccination with a DNA plasmid encoding anthrax protective antigen," *Vaccine* 17: 340-344 (1999).

GUPTA, et al., "Involvement of residues 147VYYEIGK153 in binding of lethal factor to protective antigen of *Bacillus anthracis*," *Biochem. Biophys. Res. Commun.* 280: 158-163 (2001).

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KAWABATA, et al., "The fate of plasmid DNA after intravenous injection in mice: involvement of scavenger receptors in its hepatic uptake," *Pharm. Res.* 12(6): 825-830 (1995).

KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," *Proc. Natl. Acad. Sci., USA* 89: 10277-10281 (1992).

KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," *Infect. Immunol.* 67: 5658-5663 (1999).

KRIEG, et al., "CpG DNA induces sustained IL-12 expression in vivo and resistance to *Listeria monocytogenes* challenge," *J. Immunol.* 161: 2428-2434 (1998).

KUPER, et al., "The role of nasopharyngeal lymphoid tissue," *Immunol. Today* 13(6): 219-224 (1992).

LABHASETWAR, et al., "A DNA controlled-release coating for gene transfer: transfection in skeletal and cardiac muscle," *J. Pharm. Science* 87(11): 1347-1350 (1998).

LE, et al., "Safety, tolerability and humoral immune responses after intramuscular administration of a malaria DNA vaccine to healthy adult volunteers," *Vaccine* 18: 1893-1901 (2000).

LEE, et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with *Helicobacter pylori*," *Vaccine* 17: 3072-3082 (1999).

LEPPLA, et al., "Proteolytic activation of anthrax toxin bound to cellular receptors," in Bacterial protein toxins (Fehrenbach, et al., eds) pp. 111-112, Gustav Fischer: New York (1988).

LEPPLA, "Anthrax toxin edema factor: a bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," *Proc. Natl. Acad. Sci. USA* 79: 3162-3166 (1982).

LITTLE & KNUDSON, "Comparative efficacy of *Bacillus anthracis* live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," *Infect. Immun.* 52(2): 509-512 (1986).

LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," *J. Drug. Target.* 8(1): 39-50 (2000).

LUO, et al., "Synthetic DNA delivery systems," *Nature Biotech* 18: 33-37 (2000).

/KS/

MCGHEE, et al., "The mucosal immune system: from fundamental concepts to vaccine development," *Vaccine* 10(2): 75-88 (1992).

MIKESELL, et al., "Evidence for plasmid-mediated toxin production in *Bacillus anthracis*," *Infect. Immun.* 39: 371-376 (1983).

MILNE, et al., "Anthrax protective antigen forms oligomers during intoxication of mammalian cells," *J. Biol. Chem* 269(32): 20607-20612 (1994).

NEUTRA, et al., "Antigen sampling across epithelial barriers and induction of mucosal immune responses," *Ann. Rev. Immunol.* 14: 275-300 (1996).

O'HAGAN, et al., "Controlled release microparticles for vaccine development," *Vaccine* 9: 768-771 (1991).

O'HAGAN, et al., "Long-term antibody response in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," *Vaccine* 11(9): 965-969 (1993).

PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," *J. Imm. Meth.* 195: 135-138 (1996).

PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," *J. Control. Rel.* 75: 211-224 (2001).

PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," *Vaccine* 13(15): 1427-1430 (1995).

PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," *Infect. Immunity.* 69(7): 4509-4515 (2001).

SEDEGAH, et al., "Boosting with recombinant vaccinia increases immunogenicity and protective efficacy of malaria DNA vaccine," *Proc. Nat. Acad. Sci. USA* 95: 7648-7653 (1998).

SEDEGAH, et al., "Improving protective immunity induced by DNA-based immunization: priming with antigen and GM-CSF-encoding plasmid DNA and boosting with antigen-expressing recombinant poxvirus," *J. Immun.* 164: 5905-5912 (2000).

SINGH, et al., "Controlled delivery of diphtheria toxoid using biodegradable poly(D,L-lactide) microcapsules," *Pharm. Res.* 8: 958-961 (1991).

SMITH, et al., "Induction of secretory immunity with bioadhesive poly (D,L-lactid-co-glycolide) microparticles containing *Streptococcus sobrinus* glucosyltransferase," *Oral. Microbiol. Immunol.* 15: 124-130 (2000).

/KS/

STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against *Plasmodium falciparum* malaria," *N. Engl. J. Med.* 336: 86-91 (1997).

THOMASIN, et al., "Tetanus toxoid and synthetic malaria antigen containing poly(lactide)/poly(lactide-co-glycolide) microspheres: importance of polymer degradation and antigen release for immune response," *J. Control. Rel.* 41: 131-145 (1996).

TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," *J. Control. Rel.* 66: 229-241 (2000).

TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," *Proc. 5th World Congress, Chem. Eng.* (1996).

VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," *J. Biomed. Mat. Res.* 19: 349-365 (1985).

WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four *Plasmodium falciparum* DNA plasmids," *Infect. Immunity.* 66(9): 4193-4202 (1998).

WEINER, "Oral tolerance," *Proc. Natl. Acad. Sci. USA* 91: 10762-10765 (1994).

WOLFF, et al., "Direct gene transfer into mouse muscle in vivo," *Science* 247: 1465-1468 (1990).

WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," *Immunol. Res.* 16(2): 187-201 (1997).

YEE, et al., "Loss of either CD4⁺ or CD8⁺ cells does not affect the magnitude of protective immunity to an intracellular pathogen, *Fancisella tularensis* strain LVS," *J. Immunol.* 157: 5042-5048 (1996).

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/Khatol Shahnan Shah/

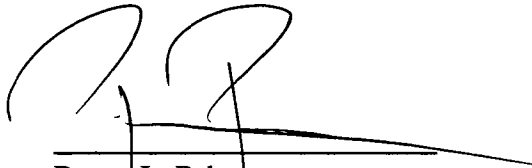
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U.S.S.N.: 10/613,975
Filed: July 3, 2003
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'P. Pabst', written over a horizontal line.

Patrea L. Pabst
Reg. No. 31,284

Dated: October 28, 2003

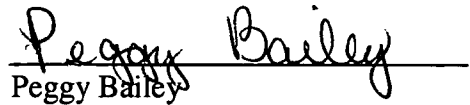
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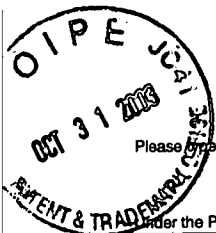
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				Application Number	
				10/613,975	
				Filing Date	
				July 3, 2003	
				First Named Inventor	
Donald L. Wise					
Group Art Unit					
1642					
Examiner Name					
Attorney Docket Number					
CSI 130					

Sheet	2	of	8
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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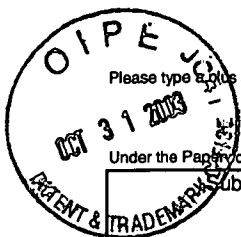
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		First Named Inventor	Donald L. Wise		
		Group Art Unit	1642		
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Sheet	3	of	8	Attorney Docket Number	CSI 130

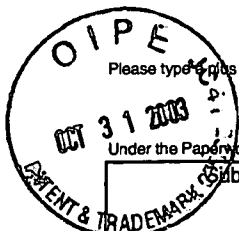
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		10/613,975			
		Filing Date			
		July 3, 2003			
		First Named Inventor			
Donald L. Wise					
Group Art Unit					
1642					
Examiner Name					
Sheet	5	of	8	Attorney Docket Number	CSI 130

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/KS/		KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci., USA</i> 89: 10277-10281 (1992).	
/KS/		KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," <i>Infect. Immunol.</i> 67: 5658-5663 (1999).	
/KS/		KRIEG, et al., "CpG DNA induces sustained 1L-12 expression in vivo and resistance to <i>Listeria monocytogenes</i> challenge," <i>J. Immunol.</i> 161: 2428-2434 (1998).	
/KS/		KUPER, et al., "The role of nasopharyngeal lymphoid tissue," <i>Immunol. Today</i> 13(6): 219-224 (1992).	
/KS/		LABHASETWAR, et al., "A DNA controlled-release coating for gene transfer: transfection in skeletal and cardiac muscle," <i>J. Pharm. Science</i> 87(11): 1347-1350 (1998).	
/KS/		LE, et al., "Safety, tolerability and humoral immune responses after intramuscular administration of a malaria DNA vaccine to healthy adult volunteers," <i>Vaccine</i> 18: 1893-1901 (2000).	
/KS/		LEE, et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with <i>Helicobacter pylori</i> ," <i>Vaccine</i> 17: 3072-3082 (1999).	
/KS/		LEPPLA, et al., "Proteolytic activation of anthrax toxin bound to cellular receptors," in <i>Bacterial protein toxins</i> (Fehrenbach, et al., eds) pp. 111-112, Gustav Fischer: New York (1988).	
/KS/		LEPPLA, "Anthrax toxin edema factor: a bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," <i>Proc. Natl. Acad. Sci. USA</i> 79: 3162-3166 (1982).	
/KS/		LITTLE & KNUDSON, "Comparative efficacy of <i>Bacillus anthracis</i> live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," <i>Infect. Immun.</i> 52(2): 509-512 (1986).	

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/KS/		LUNS福德, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug. Target.</i> 8(1): 39-50 (2000).	
/KS/		LUO, et al., "Synthetic DNA delivery systems," <i>Nature Biotech</i> 18: 33-37 (2000).	
/KS/		MCGHEE, et al., "The mucosal immune system: from fundamental concepts to vaccine development," <i>Vaccine</i> 10(2): 75-88 (1992).	
/KS/		MIKESELL, et al., "Evidence for plasmid-mediated toxin production in <i>Bacillus anthracis</i> ," <i>Infect. Immun.</i> 39: 371-376 (1983).	
/KS/		MILNE, et al., "Anthrax protective antigen forms oligomers during intoxication of mammalian cells," <i>J. Biol. Chem</i> 269(32): 20607-20612 (1994).	
/KS/		NEUTRA, et al., "Antigen sampling across epithelial barriers and induction of mucosal immune responses," <i>Ann. Rev. Immunol.</i> 14: 275-300 (1996).	
/KS/		O'HAGAN, et al., "Controlled release microparticles for vaccine development," <i>Vaccine</i> 9: 768-771 (1991).	
/KS/		O'HAGAN, et al., "Long-term antibody response in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," <i>Vaccine</i> 11(9): 965-969 (1993).	
/KS/		PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," <i>J. Imm. Meth.</i> 195: 135-138 (1996).	
/KS/		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," <i>J. Control. Rel.</i> 75: 211-224 (2001).	

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/KS/		PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," <i>Vaccine</i> 13(15): 1427-1430 (1995).	
/KS/		PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infect. Immunity</i> . 69(7): 4509-4515 (2001).	
/KS/		SEDEGAH, et al., "Boosting with recombinant vaccinia increases immunogenicity and protective efficacy of malaria DNA vaccine," <i>Proc. Nat. Acad. Sci. USA</i> 95: 7648-7653 (1998).	
/KS/		SEDEGAH, et al., "Improving protective immunity induced by DNA-based immunization: priming with antigen and GM-CSF-encoding plasmid DNA and boosting with antigen-expressing recombinant poxvirus," <i>J. Immun.</i> 164: 5905-5912 (2000).	
/KS/		SINGH, et al., "Controlled delivery of diphtheria toxoid using biodegradable poly(D,L-lactide) microcapsules," <i>Pharm. Res.</i> 8: 958-961 (1991).	
/KS/		SMITH, et al., "Induction of secretory immunity with bioadhesive poly (D,L-lactid-co-glycolide) microparticles containing <i>Streptococcus sobrinus</i> glucosyltransferase," <i>Oral. Microbiol. Immunol.</i> 15: 124-130 (2000).	
/KS/		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against <i>Plasmodium falciparum</i> malaria," <i>N. Engl. J. Med.</i> 336: 86-91 (1997).	
/KS/		THOMASIN, et al., "Tetanus toxoid and synthetic malaria antigen containing poly(lactide)/poly(lactide-co-glycolide) microspheres: importance of polymer degradation and antigen release for immune response," <i>J. Control. Rel.</i> 41: 131-145 (1996).	
/KS/		TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," <i>J. Control. Rel.</i> 66: 229-241 (2000).	
/KS/		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," <i>Proc. 5th World Congress, Chem. Eng.</i> (1996).	

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/KS/		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," <i>J. Biomed. Mat. Res.</i> 19: 349-365 (1985).	
/KS/		WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four <i>Plasmodium falciparum</i> DNA plasmids," <i>Infect. Immunity.</i> 66(9): 4193-4202 (1998).	
/KS/		WEINER, "Oral tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 91: 10762-10765 (1994).	
/KS/		WOLFF, et al., "Direct gene transfer into mouse muscle in vivo," <i>Science</i> 247: 1465-1468 (1990).	
/KS/		WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," <i>Immunol. Res.</i> 16(2): 187-201 (1997).	
/KS/		YEE, et al., "Loss of either CD4 ⁺ or CD8 ⁺ cells does not affect the magnitude of protective immunity to an intracellular pathogen, <i>Fancisella tularensis</i> strain LVS," <i>J. Immunol.</i> 157: 5042-5048 (1996).	

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